



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

June 2, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-33

Yon Tai Chung, Owner
Lotte International Trading, Inc.
240 East 4th Avenue
Anchorage, Alaska 99501

WARNNG LETTER

Dear Mr. Chung:

The Food and Drug Administration (FDA) conducted inspections of your facility located at 240 East 4th Avenue, Anchorage, Alaska, on September 24, 2003, and January 20, 2004. As part of these inspections, FDA investigators collected samples and labels for several of your products: Guyryongtang (for young girls), Guyryongtang (for young boys), Wild Sanghwang Mushroom extract (*Phellinus igniarius*), and Darin Nokyong.

These inspections reveal that your products are misbranded within the meaning of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) due to deviations from the food labeling requirements set forth in Title 21 Code of Federal Regulations Part 101 (21 CFR 101). You can find this Act and the food labeling requirements through links in FDA's homepage at www.fda.gov.

The specific violations for your products are listed below.

Guyryongtang (for young girls) and (for young boys)

- Your Guyryongtang products are misbranded within the meaning of Section 403(f) of the Act in that the net quantity of contents statement is not declared in English as required by 21 CFR 101.15(c)(1). The net quantity of contents statement must be presented in fluid ounces as required by 21 CFR 101.105(b)(2), as well as in the metric system.
- Based on a translation of your product labeling, we find that the claims concerning the treatment of colds and nosebleeds cause your products to be drugs under Section 201(g). Such claims are beyond the scope of the types of claims that are permitted on foods (e.g., structure/function claims). Articles that are intended for the diagnosis, cure, mitigation,

treatment, or prevention of a disease are drugs within the meaning of Section 201(g)(1)(B) of the Act. These claims subject your products to the requirements for “new drugs,” as defined in Section 201(p) of the Act, because there is no evidence that the product is generally recognized as effective for its intended use. Therefore, the product may not legally be marketed in the United States without an approved New Drug Application [Section 505 of the Act].

Wild Sanghwang Mushroom (extract)

- Your Wild Sanghwang Mushroom product is misbranded within the meaning of Section 403(f) of the Act in that the net quantity of contents statement is not declared in English as required by 21 CFR 101.15(c)(1). The net quantity of contents statement must be presented in fluid ounces as required by 21 CFR 101.105(b)(2), as well as in the metric system.
- Your product’s claims about counteracting poison, diarrhea, bleeding of the womb, hematuria and cancer, cause the product to be a drug under Section 201(g). Such claims are beyond the scope of the types of claims that are permitted on foods (e.g., structure/function claims). Articles that are intended for the diagnosis, cure, mitigation, treatment, or prevention of a disease are drugs within the meaning of Section 201(g)(1)(B) of the Act. These claims subject your products to the requirements for “new drugs,” as defined in Section 201(p) of the Act, because there is no evidence that the product is generally recognized as effective for its intended use. Therefore, the product may not legally be marketed in the United States without an approved New Drug Application [Section 505 of the Act].

Darin Nokyong

- The product is misbranded within the meaning of section 403(f) of the Act in that the net quantity of contents statement is not declared in English as required by 21 CFR section 101.15(c)(1). The net quantity of contents statement must be presented in fluid ounces as required by 21 CFR 101.105(b)(2), as well as in the metric system.
- Based on our translation of your product label, we have concluded that this product is misbranded within the meaning of Section 403(a)(1) of the Act in that the statement “fresh” (Korean) and “fresh” (Chinese) misrepresent the product as “fresh.” The term “fresh” is defined in 21 CFR 101.95(a) and may only be used on the label or in labeling of a food that is in its raw state and has not been subjected to any form of thermal processing except as provided in paragraph (c) of the regulation.

Lastly, we note that the serving size and number of “Servings Per Container” in the “Nutrition Facts” panel of the Guyryongtang products, Wild Sanghwang Mushroom (Extract), and Darin Nokyong are not presented in a manner required by 21 CFR 101.9(b). Title 21 CFR 101.9(b)(2)(i) states that when discrete units, such as individual foil pouches, are contained in a multi-serving package, the number of servings per container must be expressed in terms of the number of units that constitute a serving (e.g. 2 pouches). In the absence of any information

regarding the nature of these products, we are unable to determine the appropriate reference amount customarily consumed that must be used to establish the labeled serving size. However, based on the information on the labels we offer the following recommendations for these products:

- A box containing 30/40ml packages of Guyryongtang must express the serving size in terms of the individual units in the box. Accordingly, when a serving consists of "80 ml," a box containing 30/40 ml packages of Guyryongtang must express the serving size as "2 units," "2 packets," "2 packages," "2 pouches," etc. In addition, the number of servings per container must be expressed as "15."
- A box containing 30/80ml packages of Wild Sanghwang Mushroom (Extract) or Darin Nokyong must express the serving size in terms of the individual units in the box. Accordingly, when a serving consists of "80 ml," a box containing 30/80 ml packages must express the serving size as "1 unit," "1 packet," "1 package," "1 pouch," etc. In addition, the number of servings per container must be expressed as "30."

Under the Act, any substance, the intended use of which results or may reasonably be expected to result, in its becoming a component or otherwise affecting the characteristics of any food such as a food extract or tea, must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is the subject of a prior sanction for that use, or is generally recognized as safe (GRAS) among qualified experts for its intended use in foods, or is otherwise exempt from the food additive definition in Section 201(s) of the Act. A substance added to food that is not the subject of a prior sanction for that use, is not GRAS for its intended use, and is not used in accordance with a food additive regulation causes the substance and the food containing the substance to be adulterated under Section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)). Such food cannot be legally marketed in the United States. As a food manufacturer, it is your responsibility to ensure that all of the ingredients used in your food are in compliance with FDA's laws and regulations.

The above violations are not meant to be an all-inclusive list of deficiencies for your product. Other violations can subject these products to legal action. Moreover, it is your responsibility to assure that your products are labeled in compliance with the Act and regulations enforced by FDA.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions without further notice. These actions include seizure and/or obtaining a court injunction against further marketing of your products.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state the time at which corrections will be completed.

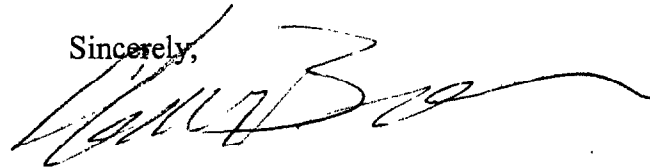
Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have

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Lotte International Trading, Inc., Anchorage, Alaska
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questions regarding any issue in this letter, please contact Lisa Elrand, Compliance Officer, at (425) 483-4913 or via e-mail at lelrand@ora.fda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: ADEC with disclosure statement